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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,442	02/12/2002	Joachim Bug	KUTZ 3	3636

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,442

Applicant(s)

BUG ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment filed 7/0/04 is acknowledged. Claims 1-10, 12-13 and 14 are being considered on the merits.

Claim 11 are withdrawn from consideration as directed to a non-elected invention.

Claims 12 and 13 are incorrectly indicated as *withdrawn*. Correction is required.

In keeping with scientific custom, the names of genera and species of microorganisms should be underlined or italicized throughout the specification and claims. To denote a proper genus, the name is capitalized and follows accepted nomenclature. Please note that "lactobacilli" and "streptococci" are improper. The proper designations are *Lactobacillus* and *Streptococcus*, respectively.

The information disclosure statement filed 7/12/02 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. The list of "non-patent literature" improperly includes a listing of Japanese patent abstracts. Correction is required, including dates of the patents.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 6 and 14 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 14 are confusing and inconsistent in the recitation of "bifidus bacteria". This is not a term of the art. The correct terminology is the genus "*Bifidobacterium*". It is noted that claims 1 and 14 pertain to "at least one genus".

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by

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"such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, at least claims 3 recites a broad recitation, and the claim also recites "preferably" and/or "~~more preferably~~" followed by the narrower statement of the range/limitation.

Claims 6 and newly added claim 14 are vague and indefinite in the use of multiple "and/or", since it is uncertain what is intended, particularly in combination with "essentially consisting of". The results of the combinations encompasses cannot be readily assessed.

Claim 14 is vague, indefinite and confusing as well as inconsistent in the recitation of "microorganisms are lactobacilli, bifidus bacteria, or streptococci, *Lactobacillus casei*, *Lactobacillus acidophilus*, *Bifidobacterium bifidum*, *Bifidobacterium longum*, and/or *Lactobacillus plantarum*". The species "*Lactobacillus casei*, *Lactobacillus acidophilus*, *Bifidobacterium bifidum*, *Bifidobacterium longum*, and/or *Lactobacillus plantarum*" are not properly "at least one genus".

Applicant did not address these rejections. Therefore, the rejections are maintained.

Claims 1-10 and 12-14 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gutttag taken with Kim *et al.* and Sigurta.

The claims are directed to an enterically coated tablet containing probiotic microorganisms having two or more layers including shellac and/or polyvinylpyrrolidone.

Gutttag discloses an enterically coated tablet containing probiotic microorganisms See, e.g., Example 1.

The reference differs from the claimed invention in that the coatings in the preferred embodiments are not disclosed as being shellac and/or polyvinylpyrrolidone and containing a further adjuvant. However, the use of these substances in coatings herein is disclosed. See, e.g., col. 10, lines 41-46 and Figures 2 and 3. The use of vinyl pyrrolidone is disclosed at col. 5, line

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11. Suitable probiotic microorganisms are recited at col. 8, lines 13-30, including strains of *Lactobacillus* and *Bifidobacterium* (*Lactobacillus bifidus*).

In addition, Kim *et al.* and Sigurta disclose probiotic compositions suitable for administration for the same purpose as the tablet of Guttag wherein shellac and materials such as hydroxymethylcellulose and glycerin are used as enteric coatings (See, e.g., Kim page 6, paragraph 2 and Sigurta, Examples).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the coated tablet of Guttag containing probiotic microorganisms according to the teachings of Guttag, Kim *et al.* and Sigurta regarding the use of a variety of coatings including shellac and/or polyvinylpyrrolidone for the expected benefit of providing a composition that maintains viability, is palatable and is impervious to degradation by stomach acid in order to provide the protection and promotion of well-being that results from effective probiotic administration.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants bald arguments that the cited references do not disclose or suggest a tablet comprising at least one genus of probiotic microorganisms, characterized in that the tablet and/or the probiotic microorganisms has/have at least one enteric coating comprising at least two layers is incorrect, given the teachings of Guttag, Kim *et al.* and Sigurta as discussed *supra*. There was both motivation and an expectation of success in the prior art cited to have successfully modified the prior art to arrive at the claimed invention. Applicant's contention that the prior art does not produce a tablet comprising probiotic microorganisms and having an enteric coating comprising at least two layers is erroneous. Kim *et al.* clearly teach at least two coatings on a tablet comprising at least : a first coating of sodium alginate and a second coating of Zein DP. See, e.g., bridging paragraph between pages 8 and 9 and Examples.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner
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